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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,880	10/16/2003	Joel E. Bernstein	41957-102729	7396

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EXAMINER	
RAMACHANDRAN, UMAMAHESWARI	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 11/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/686,880	BERNSTEIN, JOEL E.	
	Examiner	Art Unit	
	Umamaheswari Ramachandran	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-3 are pending.

Objection to Specification

The specification (p4 lines 1, 2, 12, 21) is objected to because of the following informalities: The symbol φ for the amounts of civamide listed in grams is not defined. Appropriate correction is required.

Claim Objections

Claims 1-3 are objected to because of the following informalities: The claims have been numbered improperly. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6 and 9 of copending Application No. 10/686797 in view of Yaksh et al (Science, 1979 Oct 26; 206(4417): 481-3).

The instant application teaches a method of treating or preventing painful disorders comprising administering civamide in a pharmaceutically acceptable vehicle. The copending application teaches a method of providing long-term diminishment of arthritis, neuralgia or neuropathic pain comprising administering civamide in a pharmaceutically acceptable vehicle in a single dose or as needed. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant and copending applications are drawn to a method of treating painful disorders by the administration of civamide. The instant application teaches an amount of 0.001mg to 1 mg by weight of civamide in a composition and the copending application teaches an amount of 0.001% to 1% (weight/weight). The instant application teaches a method of administering civamide intrathecally and the copending application does not teach the intrathecal administration of civamide to provide long-term diminishment of pain. However, the intrathecal administration of civamide is not excluded in claims 6 and 9 of the copending application.

Yaksh et al. teaches that a single intrathecal injection of capsaicin depletes substance P from primary sensory neurons and can cause a prolonged increase in the thermal and chemical pain thresholds (see Abstract). Hence it would have been obvious to one skilled in the art to administer civamide, a capsaicin analog intrathecally for the treatment of painful disorders.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of painful disorders such as acute nociceptive processing, post tissue injury and nerve injury induced pain by administration of civamide, does not reasonably provide enablement for preventing painful disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the Invention:

The rejected claims are drawn to a method of treating or preventing painful disorders comprising the intrathecal administration of civamide in a composition comprising a pharmaceutically acceptable vehicle.

(2) Breadth of the claims:

Claim 1 is broad as it is drawn to a method of treating or preventing painful disorders comprising the intrathecal administration of civamide in a composition comprising a pharmaceutically acceptable vehicle. The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claim.

(3) Guidance of the Specification:

The guidance given by the specification for preventing painful disorders comprising the intrathecal administration of civamide is lacking. The examples (on pages 4-5) detail the method of treatment of acute nociceptive processing, post tissue injury and nerve injury induced pain by administration of civamide.

(4) Working Examples:

The specification provides examples for the method of treatment of acute nociceptive processing, post tissue injury and nerve injury induced pain by administration of civamide. The specification does not provide any examples for the prevention of painful disorders.

(5) The relative skill of those in the art:

The relative skill of those in the medical treatment art is high, requiring advanced education and training.

(6) The predictability of art:

Claims 1 and 3 are directed to the method of treatment or prevention of painful disorders. The claim is so broad and there is a high degree of unpredictability involved. Despite the advanced training in the medical treatment arts, the arts are highly unpredictable.

(7) The Quantity of Experimentation Necessary:

In order to practice the above claimed invention, one of skill in the art would have to first envision formulation, dosage, duration, route and, in the case of human treatment, an appropriate animal model system to test the compound, civamide to determine whether or not the intrathecal administration of this compound can be used for the prevention of all painful disorders. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regarding the prevention of painful disorders by administering to a patient the compound civamide, one of skill in the art would have to envision a modification in the formulation, dosage, duration, route of administration etc. and appropriate animal model system, or envision an entirely new combination of the above and test the system again. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention of preventing painful disorders by intrathecal administration of civamide. Applicant fails to provide information sufficient to practice the claimed invention, absent undue experimentation. Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of painful disorders such as acute nociceptive processing, post tissue injury and nerve injury induced pain by administration of civamide, does not reasonably provide enablement for the treatment of all painful disorders such as pain caused by cancer, headache etc. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the Invention:

The rejected claims are drawn to a method of treating or preventing painful disorders comprising the intrathecal administration of civamide in a composition comprising a pharmaceutically acceptable vehicle.

(2) Breadth of the claims:

Claim 1 is broad as it is drawn to a method of treating or preventing painful disorders comprising the intrathecal administration of civamide in a composition comprising a pharmaceutically acceptable vehicle. The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claim.

(3) Guidance of the Specification:

The guidance given by the specification for treating all kinds of painful disorders, comprising the intrathecal administration of civamide is lacking. The examples (on pages 4-5) detail the method of treatment of acute nociceptive processing, post tissue injury and nerve injury induced pain by administration of civamide.

(4) Working Examples:

The specification provides examples for the method of treatment of acute nociceptive processing, post tissue injury and nerve injury induced pain by administration of civamide. The specification does not provide any examples for treatment of all kinds of painful disorders.

(5) The relative skill of those in the art:

The relative skill of those in the medical treatment art is high, requiring advanced education and training.

(6) The predictability of art:

Claims 1 and 3 are directed to the method of treatment or prevention of painful disorders. The claim is so broad and there is a high degree of unpredictability involved. Despite the advanced training in the medical treatment arts, the arts are highly unpredictable.

(7) The Quantity of Experimentation Necessary:

In order to practice the above claimed invention, one of skill in the art would have to first envision formulation, dosage, duration, route and, in the case of human treatment, an appropriate animal model system to test the compound, civamide to determine whether or not the intrathecal administration of this compound can be used for the treatment of all painful disorders. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regarding the treatment of all painful disorders by administering to a patient the compound civamide, one of skill in the art would have to envision a modification in the formulation, dosage, duration, route of administration etc. and appropriate animal model system, or envision an entirely new combination of the above and test the system again. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention of treating all painful disorders by intrathecal administration of civamide. Applicant fails to provide information sufficient to practice the claimed invention, absent undue experimentation. Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Bernestein et al (U.S. 5,063,060).

Bernestein teaches a method of injecting a medicinal formulation containing civamide (cis-8-methyl-N-vanillyl-6-nonenamide) in order to treat a wide range of painful and/or inflammatory disorders of man and animals such as neuropathies, skin disorders, arthritis, allergic disorders, and inflammatory bowel disorders (col. 2 lines 62-68). The reference teaches a method of treating painful disorder comprising intrathecal administration of civamide in a pharmaceutically acceptable vehicle to rats at single doses of 1 and 10 µg (col.3 example 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon et al (US 2003/0082249) in view of Bernstein et al. (U.S. 5,840,762) and Yaksh et al (Science, 1979 Oct 26;206(4417):481-3).

Gordon et al. teaches a method of treating or preventing mucositis a painful disorder by orally administering capsaicinoid such as civamide in a composition with additional agents such as carriers, preservatives, excipients etc (p2, col.2 para 0017, 0018). The reference does not teach a method of treatment or prevention of painful disorders comprising intrathecal administration of civamide.

Bernstein et al. teaches a method of treatment of myocardial disorders by the administration of civamide (zucapsaicin), in a pharmaceutically acceptable vehicle with a dosage of about 5- 500 µg/kg body weight by cerebrospinal administration (col. 2, lines 48-67). The reference also teaches that capsaicin and civamide are effective pain relievers that act on peripheral sensory neurons to deplete and prevent reaccumulation of neuropeptides, such as substance P and civamide is more potent in the depletion of neuropeptides from sensory neurons than is capsaicin. The advantage of administering civamide intrathecally is further supported by the teachings of Yaksh et al.

Yaksh et al. as above. It would have been obvious to one skilled in the art to administer civamide, a capsaicin analog intrathecally for the treatment of painful disorders. The motivation to do is provided by Yaksh et al where it teaches that a single dose administration of capsaicin via intrathecally depletes neuropeptides such as substance P from primary sensory neurons to relieve pain.

Conclusion

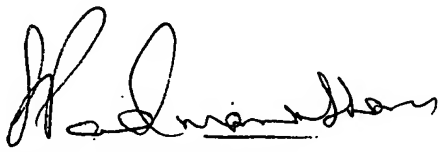
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone

number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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